

THE NATIONAL QUALITY FORUM

June 5, 2003

Dockets Management Branch, (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom it May Concern:

The National Quality Forum (NQF) commends the Food and Drug Administration (FDA) for preparing to amend its pre- and post-marketing safety reporting regulations for human drug and biological products to include bar-coding and for recognizing the need to develop definitions, reporting formats and standards for bar-coding. The NQF offers its assistance in vetting, reviewing and harmonizing proposed changes.

The NQF has followed with interest the FDA's growing interest in bar coding as a way to improve patient safety. For this initiative to be successful, the practices and standards related to bar coding will need to undergo public review and debate and gain "buy in" throughout the healthcare community. Given the controversy attendant to any change in the healthcare system, a prominent public vetting of the proposed improvements will be important, and especially for Medicare and other public programs.

The National Quality Forum (NQF), a unique public-private collaboration of approximately 180 organizations, would be pleased to assist the FDA in undertaking a public review of issues attendant to bar coding drugs and devices. The NQF was established to standardize performance measures and otherwise develop consensus on healthcare quality issues across all stakeholders, including consumers, purchasers, providers and researchers, in both the public and private sectors. You are probably familiar with some of our work, so I won't say more here in the way of background. I did want to emphasize to you that we have a keen interest in helping to standardize technologies that measurably improve patient safety and in working towards public agreement on how to focus quality improvement efforts in the arena of medication safety.

A list of NQF member organizations is attached as well as a letter that was sent to William Hubbard in October 2002, when I learned that the FDA was drafting proposed rules on bar coding for medication use in hospitals. Please let me know if the NQF can be of assistance to you in making bar coding a success.

Sincerely,



Kenneth W. Kizer, M.D., M.P.H.
President and CEO

OZN-0204

Attachments: Roster of National Quality Forum member organizations
Letter to William Hubbard, FDA, October 18, 2002

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Members

AAAHC-Institute for Quality Improvement
AARP
AFL-CIO
Agency for Healthcare Research and Quality
Alexian Brothers Medical Center
Alliance for Quality Nursing Home Care, Inc.
Alliance of Community Health Plans
American Academy of Family Physicians
American Academy of Orthopaedic Surgeons
American Academy of Physician Assistants
American Association of Health Plans
American Association of Homes and Services for the Aging
American Association of Nurse Anesthetists
American Board for Certification in Orthotics and Prosthetics
American Board of Internal Medicine Foundation
American Board of Medical Specialties
ACC/AHA Performance Measurement Task Force
American College of Cardiology
American College of Medical Quality
American College of Obstetricians and Gynecologists
Am. College of Physicians–Am. Society of Internal Medicine
American College of Radiology
American College of Surgeons
American Federation of Teachers Healthcare
American Health Care Association
American Health Quality Association
American Heart Association
American Hospice Foundation
American Hospital Association
American Medical Association
American Nurses Association
American Optometric Association
American Osteopathic Association
American Pharmacists Association Foundation
American Society for Quality–Health Care Division
American Society for Therapeutic Radiology and Oncology
American Society of Clinical Oncology
American Society of Health-System Pharmacists
Anesthesia Patient Safety Foundation
Ascension Health
Aspect Medical Systems, Inc.
Association of American Medical Colleges
Aventis Pharmaceuticals
Battelle Memorial Institute
Beacon Health Strategies
Blue Cross Blue Shield of Michigan
Buyers Health Care Action Group
California Health Decisions
California HealthCare Foundation
Cardinal Health, Inc.
Catholic Health Initiatives
Catholic Healthcare Partners
Centers for Disease Control and Prevention
Centers for Medicare & Medicaid Services
Center to Advance Palliative Care
Central Florida Health Care Coalition
Cleveland Clinic Foundation
CHRISTUS Health
CIGNA Healthcare
CMRI
College of American Pathologists
Commonwealth Fund
Community Hospital of the Monterey Peninsula
Consumer Coalition for Quality Health Care
Coral Initiative, LLC
Council of Medical Specialty Societies
CRG Medical
Delaware Health Care Commission
Delmarva Foundation
Duke University-Health Sector Management Program
eHealth Initiative
Empire Blue Cross/Blue Shield
Employer Health Care Alliance Cooperative (The Alliance)
Federation of American Hospitals
First Health, Inc.
Ford Motor Company
Forum of End Stage Renal Disease Networks
Foundation for Accountability (FACCT)
General Motors
GlaxoSmithKline
Greater Detroit Area Health Council
Greater New York Hospital Association
HCA
Health Care Excel, Inc.
HealthCare 21
HealthHelp Inc.
Healthcare Leadership Council
Health Resources and Services Administration

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Members

Health Grades, Inc.
Hudson Health Plan
Henry Ford Health System
Hoag Hospital
Horizon Blue Cross and Blue Shield of New Jersey
Illinois Department of Public Health
Institute for Safe Medication Practices
Integrated Healthcare Association
INTEGRIS Health
IPRO
The Jackson Organization
Jefferson Health, Office. of Health Policy & Clinical Outcomes
Joint Comm. on Accreditation of Healthcare Organizations
Kaiser Permanente
Leapfrog Group
Long Term Care Institute, Inc.
Los Angeles County - Department of Health Services
Loyola University Health System-Ctr for Clinical Effectiveness
Maine Health Management Coalition
March of Dimes
Mayo Foundation
Medical Review of North Carolina, Inc.
Memorial Health University Medical Center
Memorial Sloan-Kettering Cancer Center.
Midwest Business Group on Health
National Association for Healthcare Quality
National Association of Chain Drug Stores
Nat'l. Assoc. of Children's Hospitals and Related Institutions
National Association Medical Staff Services
National Association of Public Hospitals and Health Systems
National Association of State Medicaid Directors
National Business Coalition on Health
National Citizens Coalition for Nursing Home Reform
National Committee for Quality Assurance
National Committee for Quality Health Care
National Hospice and Palliative Care Organization
National Institutes of Health
National Partnership for Women and Families
National Patient Safety Foundation
National Pharmaceutical Council
National Research Corporation
Nemours Foundation
New Jersey Health Care Quality Institute, Inc.
New York Presbyterian Hospital and Health System
North Shore-Long Island Jewish Health System
Northeast Health Care Quality Foundation
Ohio KePRO
Pacific Business Group on Health
PacifiCare
Partners Healthcare System, Inc.
Physician Consortium for Performance Improvement
Premier, Inc.
Professional Research Consultants, Inc.
Qualidigm
Rhode Island and Providence Plantations, Dept. of Health
Robert Wood Johnson University Hospital - New Brunswick
Robert Wood Johnson University Hospital - Hamilton
Service Employees International Union
Schaller Anderson, Inc.
Sisters of Mercy Health System
South Nassau Communities Hospital
Spartanburg Regional Healthcare System
Spectrum Health
State University of New York, College of Optometry
Stratis Health
Substance Abuse and Mental Health Services Administration
Sutter Health
Tenet Healthcare
Texas Medical Institute of Technology
Trinity Health
Uniform Data System for Medical Rehabilitation
UnitedHealth Group
United Hospital Fund
University of Michigan Hospitals and Health Centers
University of North Carolina-Program on Health Outcomes
URAC
US Department of Defense-Health Affairs
US Food and Drug Administration
US Office of Personnel Management
US Pharmacopeia
Veterans Health Administration
VHA, Inc.
Virginia Health Quality Center
Washington Business Group on Health
West Virginia Medical Institute
Yale-New Haven Health System

THE NATIONAL QUALITY FORUM

October 18, 2002

Mr. William K. Hubbard
Senior Associate Commissioner
for Policy, Planning and Legislation
Food and Drug Administration
5600 Fishers Lane
Room 14101
Rockville, MD 20857

Dear Mr. Hubbard:

I am aware that your office is currently drafting proposed rules on bar coding for medication use in hospitals, and I want to offer assistance in two ways.

First, in determining which standards should apply for bar coding (e.g., for data encryption, etc.), I ask that you consider working with the National Quality Forum (NQF) for this specific task. Determining which bar code standards should be used seems like it would lend itself nicely to the voluntary consensus standards setting process.

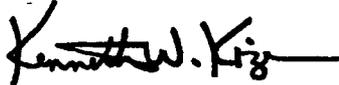
As you probably know, FDA is one of the nearly 160 NQF member organizations. Other federal members include CMS, AHRQ, NCI, CDC, NIH, VA and DOD. The NQF is a public-private entity that comports with the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119 as a voluntary consensus standards setting body. The use of voluntary consensus standards is new to healthcare, but certainly is not new in other industries. It seems to me that getting agreement, or consensus, on standards for bar coding is exactly the type of work that the NQF was created to do, and I can see several advantages to FDA in using voluntary consensus standards for bar coding, instead of FDA having to determine which standards to use. I would be happy to provide you with further information about current work that we are doing for CMS, AHRQ and NCI, if that would be helpful in your consideration.

Second, it was under my direction as Under Secretary for Health that VA launched its award winning bar code medication administration (BCMA) system. I suspect that you already have had substantial dialogue with VA about its BCMA, but if I can provide any additional perspective from my former vantage point as the CEO of the veterans healthcare system, I hope that you will not hesitate to contact me.

Hubbard
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Please feel free to call me (202.783.1300) at any time if I or the NQF can be helpful to your efforts.

Sincerely,

A handwritten signature in black ink that reads "Kenneth W. Kizer". The signature is written in a cursive style with a horizontal line at the end.

Kenneth W. Kizer, M.D., M.P.H.
President and Chief Executive Officer

cc: Steven Galson, M.D., M.P.H.
Deputy Director, Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike, HFD-001
Rockville, MD 20852